

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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UNITED STATES OF AMERICA,

Plaintiff,

v.

MICHAEL STANLEY KAPLAN, MD,

Defendant.

2:13-CR-00377-PMP-CWH

ORDER

Before the Court are Defendant Michael Stanley Kaplan's Motion to Dismiss Count One for "As Applied" Statutory Vagueness (Doc. #24), Motion to Dismiss Count One for Failure to State a Federal Offense or Invoke the Jurisdiction of the Court (Doc. #25), and Motion to Dismiss Count Two for Failure to State a Federal Offense or Invoke the Jurisdiction of the Court (Doc. #27). Magistrate Judge Hoffman issued a Report and Recommendation (Doc. #45), recommending the Court deny all three Motions. Defendant Kaplan filed Objections (Doc. #50) to the Report and Recommendation. The Court reviews de novo the Magistrate Judge's report and recommendation on dispositive motions. 28 U.S.C. § 636(b)(1)(B).

I. BACKGROUND

Defendant Kaplan is a physician who allegedly reused single-use needle guides during prostate needle biopsies he performed at Green Valley Urology. Kaplan is charged in a two-count Indictment with Conspiracy to Commit Adulteration (Count One) and False

1 Statement to a Government Agency (Count Two). Count One alleges that from
2 approximately December 2010 through March 2011, Kaplan obtained through interstate
3 commerce single-use needle guides, and Kaplan used or directed others at Green Valley
4 Urology to reuse single-use needle guides multiple times before disposing of them.
5 According to the Indictment, because of the manner in which the needle guides are used
6 during prostate needle biopsies, multiple uses of a single-use needle guide caused the guides
7 to be held under unsanitary conditions, thereby threatening the health of Kaplan's patients.
8 The Indictment alleges Kaplan did not advise his patients that a reused needle guide would
9 be used during their procedures. Count Two alleges Kaplan made a materially false
10 representation to an investigator for the Food and Drug Administration - Office of Criminal
11 Investigations when Kaplan stated that Green Valley Urology ceased reusing needle guides
12 in February 2011, when in fact Kaplan continued to direct his staff to reuse the needle
13 guides in March 2011.

14 **II. DISCUSSION**

15 **A. Motions to Dismiss Count One**

16 Defendant Kaplan is charged in Count One with conspiracy to commit the crime
17 of adulteration in violation of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21
18 U.S.C. §§ 331(k), 333(a)(2), and 351(a)(2)(A). Section 331(k) prohibits:

19 The alteration, mutilation, destruction, obliteration, or removal of the
20 whole or any part of the labeling of, or the doing of any other act with
21 respect to, a food, drug, device, tobacco product, or cosmetic, if such
22 act is done while such article is held for sale (whether or not the first
23 sale) after shipment in interstate commerce and results in such article
24 being adulterated or misbranded.

25 Section 333(a)(2) makes the offense a felony if the defendant commits the violation "with
26 the intent to defraud or mislead." Section 351(a)(2)(A) provides that a device is adulterated
"if it has been prepared, packed, or held under insanitary conditions whereby it may have
been contaminated with filth, or whereby it may have been rendered injurious to health."

1 Kaplan moves to dismiss Count One, arguing that the offense requires the
2 allegedly adulterated medical device be “held for sale,” and there is no allegation in the
3 Indictment that Kaplan sold the needle guides or held them for sale to patients. Rather,
4 Kaplan used the devices during the conduct of his medical practice. Kaplan contends that
5 given the ordinary meaning of “sale” to involve a transfer of title to another for a price, the
6 statute is unconstitutionally vague to the extent the Government seeks to apply it to a
7 physician’s use of a medical device during a medical diagnostic procedure. Kaplan also
8 argues that for the same reasons, the Indictment fails to allege the essential element of “held
9 for sale.” Alternatively, Kaplan contends that if the phrase “held for sale” includes a
10 physician’s use of a device during a medical procedure, the Indictment attempts to usurp
11 State jurisdiction over the regulation of the practice of medicine and the prosecution of
12 crimes related thereto. Finally, Kaplan argues the Indictment fails to allege a felony
13 because the Indictment does not allege he acted with the intent to defraud or mislead.

14 The Government responds that the statute is not unconstitutionally vague because
15 a reasonable person of ordinary intelligence would understand that the phrase “held for
16 sale” includes a physician’s use of a medical device during a procedure for which he
17 charges the patient for his services. The Government argues this reflects the FFDCA’s
18 purpose of regulating the safety of medical devices up to the moment the device is delivered
19 to the ultimate consumer. The Government also argues that reading the statute to apply to
20 devices used during a physician’s for-profit practice does not usurp the State’s power to
21 regulate the practice of medicine. Finally, the Government contends Count One alleges a
22 felony because it alleges Kaplan concealed from his patients that a reused needle guide
23 would be used in their procedures. The Government further contends that the Indictment
24 alleges Kaplan took other steps, including lying to investigators, the public, and his patients,
25 to conceal his activities, and he did so to enrich himself. The Government also notes that
26 even if Kaplan were correct, that would not result in dismissal, it would merely limit Count

1 One to a misdemeanor charge.

2 1. Held for Sale

3 Kaplan challenges § 331(k) as void for vagueness as applied to the facts in his
4 case. Specifically, Kaplan contends that the statute requires the adulterated device to be
5 “held for sale,” and the needle guides were not held for sale because Kaplan never
6 transferred ownership to the patients; rather, he kept the needle guides after the procedures.
7 Kaplan thus contends he did not hold the needle guides for sale, and the statute is
8 unconstitutionally vague if it applies to this conduct.

9 “A criminal statute is void for vagueness if it is not sufficiently clear to provide
10 guidance to citizens concerning how they can avoid violating it and to provide authorities
11 with principles governing enforcement.” United States v. Zhi Yong Guo, 634 F.3d 1119,
12 1121 (9th Cir. 2011) (quotation omitted). Where, as here, the defendant makes an
13 as-applied challenge, “a statute is unconstitutionally vague if it fail[s] to put a defendant on
14 notice that his conduct was criminal.” United States v. Harris, 705 F.3d 929, 932 (9th Cir.
15 2013) (quotation omitted). “As a corollary to the vagueness doctrine, where the statute is
16 ambiguous, the rule of lenity must be applied to restrict criminal statutes to conduct clearly
17 covered by those statutes.” United States v. Wyatt, 408 F.3d 1257, 1260 (9th Cir. 2005)
18 (quotation omitted).

19 When determining a statute’s meaning, the Court first looks first to the statute’s
20 plain language. Transwestern Pipeline Co., LLC v. 17.19 Acres of Prop. Located in
21 Maricopa Cnty., 627 F.3d 1268, 1270 (9th Cir. 2010). Unless the statute defines terms or
22 phrases, the Court interprets the words “as taking their ordinary, contemporary, common
23 meaning.” Id. (quoting Perrin v. United States, 444 U.S. 37, 42 (1979)). The Court also
24 examines “the structure of the statute as a whole, including its object and policy.” United
25 States v. Williams, 659 F.3d 1223, 1225 (9th Cir. 2011). If the statute’s plain meaning is
26 unambiguous, that meaning controls. Id.

1 The FFDCA does not define the phrase “held for sale.” The United States Court
2 of Appeals for the Ninth Circuit addressed the phrase “held for sale” in United States v.
3 Geborde, 278 F.3d 926 (9th Cir. 2002). In Geborde, the defendant made gamma hydroxy
4 butyrate (“GHB”) and gave it away to his friends. Geborde, 278 F.3d at 927-28. The
5 defendant argued § 331(k) did not apply to his conduct because he never sold it nor held it
6 for sale, instead he gave it away for free. Id. at 930-32. The Ninth Circuit agreed,
7 contrasting other cases which “clearly involve commercial transactions, commercial actors,
8 and commercial products,” as compared to the defendant’s conduct of “distribut[ing the
9 drug] free of charge to friends.” Id. at 931. In reaching this conclusion, the Geborde Court
10 stated “[i]t seems clear to us that the phrase ‘held for sale’ plainly contemplates a sale.” Id.
11 at 932.

12 Geborde thus stands for the proposition that the phrase “held for sale” must
13 contain a commercial component. Geborde did not address whether a single-use medical
14 device is held for sale when a physician uses that device during treatment of his patients in
15 the course of his for-profit medical practice. Those courts that have addressed the issue
16 have concluded that physicians hold for sale drugs and devices used in the treatment of their
17 patients. See, e.g., United States v. Evers, 643 F.2d 1043, 1050 (5th Cir. 1981) (“Doctors
18 holding drugs for use in their practice are clearly one part of the distribution process, and
19 doctors may therefore hold drugs for sale within the meaning of section 301(k) of the
20 Act.”); United States v. Diapulse Corp. of Am., 514 F.2d 1097, 1098 (2d Cir. 1975)
21 (holding that “devices held by practitioners” and “used in the treatment of patients, may
22 properly be considered ‘held for sale’ within the meaning of the Food, Drug, and Cosmetic
23 Act”). This interpretation of the phrase “held for sale” is consistent with the FFDCA’s
24 overall structure and purpose of “protect[ing] consumers from dangerous products . . . from
25 the moment of their introduction into interstate commerce all the way to the moment of
26 their delivery to the ultimate consumer.” United States v. Sullivan, 332 U.S. 689, 696

1 (1948). The Court agrees with these courts and with Magistrate Judge Hoffman's Report
2 and Recommendation, and holds that the ordinary and common meaning of "held for sale"
3 within the meaning of § 331(k) includes single use devices used in the course of treating a
4 paying patient.

5 On de novo review, the Court adopts Magistrate Judge Hoffman's analysis and
6 conclusion that the Indictment is not unconstitutionally vague as applied to the facts alleged
7 in the Indictment, and the Indictment sufficiently alleges Kaplan held the needle guides for
8 sale. As explained by Magistrate Judge Hoffman, the Indictment summarizes the statutory
9 language and uses the phrase "held for sale." (Report & Recommendation (Doc. #45) at 6.)
10 Additionally, the Indictment sufficiently alleges Kaplan was engaged in commercial
11 transactions by operating his medical practice, and patients' payment for medical services
12 "undoubtedly reflects the costs of materials used to provide the unique medical service.
13 When a single use needle guide is used for a patient's biopsy, its value and usefulness as a
14 medical device is transferred from Kaplan to the patient in exchange for payment." (*Id.* at
15 8, 11.) As a result, the patient, not Kaplan, is the ultimate consumer of the single use needle
16 guide. The fact that Kaplan reused the needle guides despite their labeling as single use
17 "does not remove [them] from being used as part of the commercial transaction to obtain
18 medical services paid for by the patient." (*Id.* at 8.) Additionally, the fact that the needle
19 guides were labeled as single use put Kaplan on notice that the patient in each procedure,
20 not Kaplan, was the ultimate consumer of the single use device. (*Id.* at 11.) The Court
21 therefore adopts the Magistrate Judge's Report and Recommendation, and overrules
22 Kaplan's objection that the statute as applied is void for vagueness.

23 2. Failure to Invoke Federal Jurisdiction

24 Kaplan argues that if the statute reaches his conduct in this case, then the statute
25 fails to invoke federal jurisdiction because it would impermissibly intrude on regulation of
26 the practice of medicine, a matter that is reserved exclusively to the States. Kaplan argues

1 that as a physician, he is entitled to make off-label use of medical devices and drugs, and
2 his reuse of the needle guides is an off-label use that is subject only to State regulation of
3 the practice of medicine.

4 After de novo review, the Court overrules Kaplan's objections and adopts
5 Magistrate Judge Hoffman's analysis of this issue. (*Id.* at 12-13.) Although the regulation
6 of the practice of medicine generally lies within the States' police powers, the FFDCA's
7 regulation of the distribution of drugs and medical devices in general does not
8 impermissibly usurp the States' power. (*Id.* at 12 (citing *United States v. Sullivan*, 332 U.S.
9 689 (1948); *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir.
10 2014); & 21 U.S.C. § 396).) Nor does the Indictment in this case improperly seek to invade
11 the State of Nevada's regulation of the practice of medicine. As stated by Magistrate Judge
12 Hoffman, "the Government's focus is upon the conspiracy to adulterate the single use
13 needle guide held for sale to the patient, not the procedure used to conduct the biopsy with a
14 needle guide." (Report & Recommendation at 12.)

15 3. Intent to Defraud or Mislead

16 An offense under § 331(k) is a misdemeanor, but if the defendant commits the
17 violation "with the intent to defraud or mislead," then it is a felony. 21 U.S.C. § 333(a).
18 Kaplan contends the Indictment fails to allege he acted with the intent to defraud or
19 mislead.

20 As an initial matter, even if Kaplan were correct, the Court would not dismiss
21 Count One. Rather, Kaplan would face a misdemeanor charge instead of a felony charge.
22 Additionally, the Court overrules Kaplan's objections and adopts Magistrate Judge
23 Hoffman's Report and Recommendation on this issue. (Report & Recommendation at 8-
24 10.) The Indictment cites to § 331(a)(2), which is the specific provision making the crime
25 punishable as a felony if done with the intent to defraud or mislead. The Indictment also
26 contains factual allegations that Kaplan sought to enrich himself through reuse of the single

1 use needle guides, that he concealed the reuse of the needle guides from his patients, that he
2 took other affirmative steps to conceal his conduct, and that he did so to enrich himself at
3 his patients' expense. (Indictment at ¶¶ 1, 14, 17F, 17G, 17H, 17I; Report &
4 Recommendation at 9-10.) The Indictment therefore sufficiently notifies Kaplan that he is
5 charged with a felony.

6 **B. Motion to Dismiss Count Two**

7 Kaplan is charged in Count Two of the Indictment with knowingly and willfully
8 making a materially false statement in a matter within the jurisdiction of a federal agency
9 under 18 U.S.C. § 1001(a)(2). Kaplan moves to dismiss Count Two on the basis that it does
10 not invoke federal jurisdiction, and that it fails to allege the essential elements of the
11 charged offense.

12 1. Federal Jurisdiction

13 Kaplan argues that because Count One usurps state regulation of the practice of
14 medicine, Count Two fails to allege Kaplan made a materially false statement in a matter
15 within the jurisdiction of a federal agency. As a result, Kaplan contends Count Two fails to
16 state an offense under 18 U.S.C. § 1001(a)(2), and does not invoke the Court's jurisdiction.

17 The Court already rejected Kaplan's argument that Count One usurps state
18 regulation of the practice of medicine. Additionally, the Indictment alleges Kaplan made a
19 false statement within the jurisdiction of the Food and Drug Administration ("FDA"). The
20 FDA has jurisdiction to investigate violations of the FFDCA, including the adulteration of
21 medical devices such as the single use needle guides as alleged in the Indictment. See 21
22 U.S.C. §§ 321(h), 351, 372(a)(1)(A). The Court therefore will overrule Kaplan's objection
23 and affirm the Magistrate Judge's Report and Recommendation on this point. (Report &
24 Recommendation at 14-15.)

25 2. Sufficiency of the Indictment

26 Kaplan argues Count Two fails to allege Kaplan knew he was committing a

1 federal offense by making a materially false statement to a federal agency, and therefore
2 fails to state an offense under § 1001(a)(2). Kaplan also argues Count Two fails to allege
3 facts showing the alleged misstatement was material.

4 “An indictment or information must meet the requirements of both the Due
5 Process Clause and Federal Rule of Criminal Procedure 7.” United States v. Huping Zhou,
6 678 F.3d 1110, 1113 (9th Cir. 2012). For an indictment to be sufficient under the Due
7 Process Clause, the indictment must “contain[] the elements of the offense charged and
8 fairly inform[] a defendant of the charge against which he must defend.” Id. (quotation
9 omitted). Additionally, the indictment must enable the defendant “to plead an acquittal or
10 conviction in bar of future prosecutions for the same offense.” Id. (quotation omitted).
11 Federal Rule of Criminal Procedure 7(c)(1) requires an indictment to “be a plain, concise,
12 and definite written statement of the essential facts constituting the offense charged.” An
13 indictment is sufficient if it “tracks the words of the statute charging the offense, . . . so long
14 as the words unambiguously set forth all elements necessary to constitute the offense.”
15 United States v. Davis, 336 F.3d 920, 922 (9th Cir. 2003) (quotation omitted).

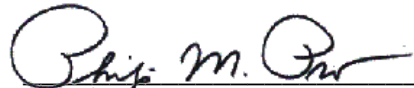
16 Count Two charges Kaplan with violating 18 U.S.C. § 1001. Section 1001(a)(2)
17 makes it unlawful to knowingly and willfully make a materially false statement in a matter
18 within the jurisdiction of a federal agency. Count Two of the Indictment tracks the
19 statutory language by alleging Kaplan “did knowingly and willfully make and cause to be
20 made a materially false, fictitious, and fraudulent statement and representation in a matter
21 within the jurisdiction of a federal agency, the Food and Drug Administration - Office of
22 Criminal Investigations.” (Indictment at 6.) The Indictment also contains factual
23 allegations regarding the date of the alleged false statement, the content thereof, and to
24 whom the statement was made. (Id.) The Indictment thus alleges the essential elements of
25 the offense charged, fairly informs Kaplan of the essential facts of the charge against which
26 he must defend, and enables Kaplan to plead double jeopardy. The Court therefore

1 overrules Kaplan's objections regarding knowledge and materiality, and affirms the
2 Magistrate Judge's Report and Recommendation on these issues. (Report &
3 Recommendation at 15-16.)

4 **III. CONCLUSION**

5 IT IS THEREFORE ORDERED that Defendant Michael Stanley Kaplan's
6 Objections to the Findings and Recommendation of the Magistrate Judge Regarding
7 Defendant's Motions to Dismiss (Doc. #50) are hereby OVERRULED and the Report and
8 Recommendation of the Magistrate Judge (Doc. #45) is hereby AFFIRMED.

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10 DATED: September 5, 2014


PHILIP M. PRO
United States District Judge